5. 510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

MAR 19 2013

APPLICANT	Sequent Medical, Inc. 11A Columbia Aliso Viejo, CA 92656 Tel: (949) 830-9600 Fax: (949) 830-9658
OFFICIAL CORRESPONDENT	Melanie Parravi 11A Columbia Aliso Viejo, CA 92656 melaniep@sequentmedical.com Tel: (949) 830-9600 x 130 Fax: (949) 830-9568
TRADE NAME	VIA™ Microcatheter
COMMON NAME	Percutaneous Catheter, Continuous Flush catheter
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1250 and §870.1210
PRODUCT CODES	DQY: Percutaneous Catheter KRA: Continuous Flush Catheter
PREDICATE DEVICES	Marksman Catheter (K091559) Excelsior XT-27 Microcatheter (K113778)

SUBSTANTIALLY EQUIVALENT TO:

The VIA™ Microcatheter is substantially equivalent to the previously cleared Marksman™ Catheter (K091559) and Excelsior XT-27 Microcatheter (K113778).

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The VIA™ Microcatheter and VIA™ PLUS Microcatheter are designed to be introduced over a steerable guidewire into the vasculature. The physician inserts the catheter into the vein or artery through the skin (percutaneous) using a sheath or guidewire. The device can then be navigated to the treatment site. Navigation is aided by the coated surface of the catheter which assists with manipulation while in the vasculature. Throughout the procedure the physician can obtain the position of the catheter by the tip marker using fluoroscopic techniques. Diagnostic, therapeutic and interventional devices can be delivered through the lumen of the catheter to the treatment site.

The VIA™ Microcatheter is a sterile single lumen device with one distal tip marker designed to aid the physician in accessing distal vasculature when used with a guide

catheter and steerable guidewire. Variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over selectively placed guidewires. The proximal end of the catheter incorporates a standard luer adapter to facilitate attachment of accessories. A single radiopaque marker positioned at the distal tip facilitates fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic coating which reduces friction during manipulation in the vessel. The inner lumen of the catheter has a PTFE liner which assists with delivery of interventional devices, such as an intraluminal flow diverter.

The VIA™ and VIA™ PLUS Microcatheter is available in effective lengths of 154 cm and 133 cm and inner diameters of 0.27 inches and 0.33 inches respectively. For commercialization purposes the 0.027 inch diameter will be named the VIA™ Microcatheter and the 0.033 inch diameter will be named the VIA™ PLUS Microcatheter.

The VIA™ Microcatheter is presented in a tyvek pouch and is sterile, single use only and non-pyrogenic.

Accessories: Each VIA™ Microcatheter is provided with a shaping mandrel to facilitate distal tip shaping.

In intravascular procedures, the device assists the physician in:

- Accessing the targeted vasculature to facilitate the delivery of interventional devices, such as intraluminal flow diverters, infusion of diagnostic agents such as contrast and infusion of therapeutic agents.

INDICATIONS FOR USE:

The VIA™ Microcatheter has the same indications for use as the previously cleared Predicate Marksman™ Catheter (K091559) and the Excelsior XT-27 Microcatheter (K113778). Thus, the Indications for Use are as follows:

The VIA™ Microcatheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral and coronary vasculature.

Example of indications for use from currently marketed catheters include but are not limited to:

- The Marksman™ Catheter (K091559) is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral and coronary vasculature.
- The Excelsior XT-27 Microcatheter (K113778) is intended to assist in the delivery of diagnostic agents (such as contrast media), therapeutic agents, and non-liquid interventional devices (such as stents) that are indicated for use in the neurovasculature and with a catheter of 0.027 inches in diameter.

SECTION 5. 510(K) SUMMARY

TECHNICAL CHARACTERISTICS:

The VIA™ Microcatheter incorporates variable shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aid the physician in tracking over selectively placed guidewires. The inner lumen incorporates a PTFE liner to facilitate movement of devices through the catheter's lumen to the intended destination in the vasculature. The outer surface of the catheter is coated with a hydrophilic coating which reduces friction during manipulation in the vessel. The tip of the catheter can be steam shaped by physician for proper adjustment to the anatomy prior to use.

PERFORMANCE DATA:

Device performance testing confirms that the VIA™ Microcatheter can be used according to its intended use. The VIA™ Microcatheter has been verified and validated according to Sequent Medical's procedures for product design and development. Performance testing included:

- Bench Testing
- Sterilization Validation
- Packaging and shelf life testing
- Biocompatibility testing
- Simulated use testing in Animals

This testing regime demonstrates that the subject device is substantially equivalent to the legally marketed predicate device, for its intended use in the introduction of interventional devices, infusion of diagnostic and therapeutic agents into the vasculature.

The information provided by Sequent Medical in this 510(k) application was found to be substantially equivalent to both the predicate devices, including the Marksman™ Catheter (K091559), and Excelsior XT-27 Microcatheter (K113778).

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

A technological comparison and bench, and simulated use testing demonstrate the substantial equivalence of the VIA™ Microcatheter to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

March 19, 2013

Sequent Medical, Inc
C/O Melanie Parravi
11A Columbia
Aliso Viejo, CA 92656 US

Re: K123477
Trade/Device Name: Via Microcatheter, Via Plus Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, DQY
Dated: January 15, 2013
Received: January 23, 2013

Dear Ms. Parravi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K123477 (This application)

Device Name: VIA™ Microcatheter and VIA™ PLUS Microcatheter

Indications for Use:

The VIA™ Microcatheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the peripheral and coronary vasculature.

Prescription Use x (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner